

# Policy on Blood Donor Screening, Deferral, and Lookback for West Nile Virus (WNV)

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**Purpose** Establish revised policy regarding blood donor screening, deferral and lookback for West Nile Virus. This policy applies to collections of Whole Blood, blood components (including recovered plasma), Source Plasma and Source Leukocytes collected from allogeneic and autologous donors intended either for use in transfusion or for further manufacture into injectable and non-injectable products. Services should update applicable Standardized Operating Procedures (SOP) in accordance with (IAW) this policy.

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**Background** WNV is primarily transmitted in birds through mosquito bites. Humans are incidental hosts. WNV is associated with human encephalitis and meningitis. In 2002, a major outbreak of WNV was detected in many parts of the United States. The number of human cases of WNV illness in 2002 totaled 4161 and 277 deaths were reported as of March 12, 2003. The 2002 WNV epidemic involved the first documented cases of WNV transmission through blood transfusion, organ transplantation, intrauterine infection, and possibly breastfeeding. Since 80% of persons infected with WNV do not develop any illness and remain asymptomatic, even while transiently viremic, careful predonation screening and WNV testing of blood and plasma donors for WNV is necessary to reduce the risk of WNV infection through blood transfusion.

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**Definitions** The following definitions apply to WNV in this policy:

Term	Definition
<b>Symptoms of WNV Infection</b>	<ul style="list-style-type: none"><li>• Measured fever [temperature greater than 100.4 °F (38°C)] <b>AND</b></li><li>• One or more flu-like symptom suggestive of WNV infection (e.g. headache, eye pain, body aches, generalized weakness, new generalized skin rash, swollen lymph nodes)</li><li>• Additional information available on CDC website: <a href="http://www.cdc.gov/ncidod/dybid/westnile/clinical_guidance.htm">http://www.cdc.gov/ncidod/dybid/westnile/clinical_guidance.htm</a> OR <a href="http://www.cdc.gov/ncidod/dybid/westnile/city_states.htm">www.cdc.gov/ncidod/dybid/westnile/city_states.htm</a></li></ul>

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# Policy on Blood Donor Screening, Deferral, and Lookback for West Nile Virus (WNV), Continued

## Definitions (continued)

Term	Definition
<b>Measured Fever</b>	<ul style="list-style-type: none"> <li>• Temperature greater than 100.4 °F (38°C)</li> </ul>
<b>Medical Diagnosis of WNV Infection</b>	<ul style="list-style-type: none"> <li>• Current or recent illness compatible with WNV <b>AND</b></li> <li>• Positive test for WNV IgM antibodies</li> </ul>
<b>Suspect Donation(s)</b>	<ul style="list-style-type: none"> <li>• The collection(s) from which an infected recipient received a blood component</li> </ul>
<b>Donors At Risk of Transmitting WNV</b>	<ul style="list-style-type: none"> <li>• Measured fever with headache or with other WNV symptoms within 7 days prior to and 14 days after donation</li> <li>• Recent diagnosis of WNV infection <b>AND</b> donated blood within 14 days prior to and 28 days after onset of symptoms</li> <li>• Recent confirmed positive test for WNV NAT</li> <li>• Determined to be potentially associated with a case of transfusion transmitted WNV</li> </ul>
<b>Donors Potentially Associated with Transfusion Transmitted WNV</b>	<ul style="list-style-type: none"> <li>• A recipient is later diagnosed with WNV <b>AND</b></li> <li>• The recipient received blood components from the donor within 28 days before the onset of symptoms in the recipient.</li> </ul>
<b>Patients Potentially Associated with Transfusion Transmitted WNV</b>	<ul style="list-style-type: none"> <li>• Diagnosis of WNV infection <b>AND</b></li> <li>• Received blood transfusions or organs within 28 days preceding onset of symptoms</li> </ul>

## Donor Screening and Deferral

Perform the following 8 steps to screen the donor for possible WNV infection.

Step	Action
1	Provide each allogeneic and autologous donor with the WNV information contained in Attachment A. <b>NOTE:</b> Services may choose to modify the format of Attachment A or combine the information with other donor information sheets.

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# Policy on Blood Donor Screening, Deferral, and Lookback for West Nile Virus (WNV), Continued

## Donor Screening and Deferral (continued)

Step	Action										
2	Ask the donor if they read and understood the WNV information provided to them.										
	<table> <tr> <th>If the donor ...</th><th>Then ...</th></tr> <tr> <td>Understands the WNV information provided</td><td>Continue</td></tr> <tr> <td>Does NOT understand the WNV information provided</td><td>Explain and answer any questions for the donor</td></tr> </table>	If the donor ...	Then ...	Understands the WNV information provided	Continue	Does NOT understand the WNV information provided	Explain and answer any questions for the donor				
If the donor ...	Then ...										
Understands the WNV information provided	Continue										
Does NOT understand the WNV information provided	Explain and answer any questions for the donor										
3	Ask the donor the following WNV screening question: <b>“In the past 7 days, have you had an unexplained, measured fever of greater than 100.4 °F (38°C) associated with a headache”?</b>										
4	Determine whether or not the donor is deferred for possible WNV:										
	<table> <tr> <th>If the donor ...</th><th>Then the donor is ...</th></tr> <tr> <td>Answers <b>NO</b> to the WNV screening question</td><td><b>NOT</b> deferred for WNV infection</td></tr> <tr> <td>Answers <b>YES</b> to the WNV screening question</td><td><b>Deferred for 28 days</b> from the date of interview</td></tr> <tr> <td>Has a history of or reports a confirmed positive test for WNV NAT on any previous donation</td><td><b>Deferred temporarily</b> until re-instated in accordance with the WNV NAT testing protocol and Service-specific SOPs. The donor <b>may NOT be re-instated any sooner than 28 days</b> after the date of the confirmed positive donation.</td></tr> <tr> <td>Had a recent diagnosis of WNV infection</td><td><b>Deferred for 28 days</b> from the onset of illness or 14 days after the condition is considered to be resolved, whichever date is later.</td></tr> </table>	If the donor ...	Then the donor is ...	Answers <b>NO</b> to the WNV screening question	<b>NOT</b> deferred for WNV infection	Answers <b>YES</b> to the WNV screening question	<b>Deferred for 28 days</b> from the date of interview	Has a history of or reports a confirmed positive test for WNV NAT on any previous donation	<b>Deferred temporarily</b> until re-instated in accordance with the WNV NAT testing protocol and Service-specific SOPs. The donor <b>may NOT be re-instated any sooner than 28 days</b> after the date of the confirmed positive donation.	Had a recent diagnosis of WNV infection	<b>Deferred for 28 days</b> from the onset of illness or 14 days after the condition is considered to be resolved, whichever date is later.
If the donor ...	Then the donor is ...										
Answers <b>NO</b> to the WNV screening question	<b>NOT</b> deferred for WNV infection										
Answers <b>YES</b> to the WNV screening question	<b>Deferred for 28 days</b> from the date of interview										
Has a history of or reports a confirmed positive test for WNV NAT on any previous donation	<b>Deferred temporarily</b> until re-instated in accordance with the WNV NAT testing protocol and Service-specific SOPs. The donor <b>may NOT be re-instated any sooner than 28 days</b> after the date of the confirmed positive donation.										
Had a recent diagnosis of WNV infection	<b>Deferred for 28 days</b> from the onset of illness or 14 days after the condition is considered to be resolved, whichever date is later.										

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# Policy on Blood Donor Screening, Deferral, and Lookback for West Nile Virus (WNV), Continued

## Donor Screening and Deferral (continued)

Step	Action				
	<table> <tr> <th>If the donor ...</th><th>Then the donor is ...</th></tr> <tr> <td>Has been notified that a previous donation is potentially associated with transfusion transmitted WNV infection</td><td><b>Deferred for 28 days</b> from the date of the implicated donation</td></tr> </table>	If the donor ...	Then the donor is ...	Has been notified that a previous donation is potentially associated with transfusion transmitted WNV infection	<b>Deferred for 28 days</b> from the date of the implicated donation
If the donor ...	Then the donor is ...				
Has been notified that a previous donation is potentially associated with transfusion transmitted WNV infection	<b>Deferred for 28 days</b> from the date of the implicated donation				
5	Document whether or not the donor is deferred for possible WNV infection IAW Service-specific SOPs.				
6	If donor is deferred, enter deferral in DBSS using DBSS Temporary Deferral Code 906.				
7	<p>Encourage donors to report any information listed below that later becomes known to them after their donation:</p> <ul style="list-style-type: none"> <li>• Unreported measured fever of greater than 100.4 °F (38°C) associated with headache, occurring within 7 days prior to donation.</li> <li>• Unexplained measured fever of greater than 100.4 °F (&gt;38°C) associated with headache or associated with other symptoms suggestive of WNV infection, occurring within 14 days after donation.</li> <li>• Notification that one of their blood donations tested confirmed positive for WNV NAT.</li> <li>• Recent diagnosis of WNV infection.</li> <li>• Notification that one of their donations is suspected of being potentially associated with transfusion transmitted WNV infection in a transfusion recipient.</li> </ul>				

## WNV Testing

When WNV test kits are available for use, perform the following 5 steps to test all homologous and autologous donors for possible WNV infection.

**NOTE:** Tests will be performed using the nucleic acid testing (NAT) methodology, will initially be performed under investigational procedures, and will subsequently be performed using a licensed test when available.

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## Policy on Blood Donor Screening, Deferral, and Lookback for West Nile Virus (WNV), Continued

### WNV Testing (continued)

Step	Action						
1	Test the donation for WNV in accordance with NAT testing protocols and Service-specific SOPs.						
2	Determine if the donor is confirmed positive for WNV in accordance with NAT testing protocols.						
3	Use the following criteria for product management and donor deferral based on the results of WNV NAT.						
	<table> <tr> <th>If the donor....</th><th>Then...</th></tr> <tr> <td>Tests <b>negative</b> for WNV NAT</td><td> <ul style="list-style-type: none"> <li>• <b>Make blood components available</b> and do not defer donor</li> </ul> </td></tr> <tr> <td>Tests <b>confirmed positive</b> for WNV NAT</td><td> <ul style="list-style-type: none"> <li>• <b>Quarantine and destroy</b> all components</li> <li>• <b>Temporarily defer donor</b> until re-instated in accordance with WNV NAT testing protocols and Service-specific SOPs. The donor <b>may NOT be re-instated any sooner than 28 days</b> after the date of the confirmed positive donation.</li> </ul> </td></tr> </table>	If the donor....	Then...	Tests <b>negative</b> for WNV NAT	<ul style="list-style-type: none"> <li>• <b>Make blood components available</b> and do not defer donor</li> </ul>	Tests <b>confirmed positive</b> for WNV NAT	<ul style="list-style-type: none"> <li>• <b>Quarantine and destroy</b> all components</li> <li>• <b>Temporarily defer donor</b> until re-instated in accordance with WNV NAT testing protocols and Service-specific SOPs. The donor <b>may NOT be re-instated any sooner than 28 days</b> after the date of the confirmed positive donation.</li> </ul>
If the donor....	Then...						
Tests <b>negative</b> for WNV NAT	<ul style="list-style-type: none"> <li>• <b>Make blood components available</b> and do not defer donor</li> </ul>						
Tests <b>confirmed positive</b> for WNV NAT	<ul style="list-style-type: none"> <li>• <b>Quarantine and destroy</b> all components</li> <li>• <b>Temporarily defer donor</b> until re-instated in accordance with WNV NAT testing protocols and Service-specific SOPs. The donor <b>may NOT be re-instated any sooner than 28 days</b> after the date of the confirmed positive donation.</li> </ul>						
4	If donor is deferred, document donor deferral for WNV NAT in accordance with Service-specific SOPs.						
5	If donor is deferred, enter deferral in DBSS using DBSS Temporary Deferral Code 906.						

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# Policy on Blood Donor Screening, Deferral, and Lookback for West Nile Virus (WNV), Continued

## Lookback and Post Donation Information

Perform the following 7 steps for donor and patient lookback when a donor tests confirmed positive for WNV NAT or WNV related post donation information (PDI) is received.

**NOTE:** Quarantine and retrieval of previously collected components applies to collections of Whole Blood and blood components intended for transfusion, as well as unpooled Source plasma, recovered plasma, and Source Leukocytes intended for further manufacturing into injectable and non-injectable products. Quarantine and retrieval is not recommended for those products that have been pooled for fractionation.

Step	Action										
1	Perform the following steps for product identification/retrieval:										
	<table> <tr> <th>If PDI is received about ...</th><th>Then promptly identify and locate all in-date products...</th></tr> <tr> <td> <ul style="list-style-type: none"> <li>• Donors with mild symptoms of upper respiratory infection unassociated with fever <b>OR</b></li> <li>• Donors with only mosquito bites</li> </ul> </td><td>NOT required or recommended.</td></tr> <tr> <td>Donors with an unexplained measured fever of &gt;100.4 °F (&gt;38°C) associated with headache or associated with other symptoms suggestive of WNV infection, occurring within 7 days prior to or 14 days after donation.</td><td>Collected within 14 days prior to and 28 days after the onset of symptoms in donor.</td></tr> <tr> <td>Donors testing confirmed positive for WNV NAT on a blood donation.</td><td>Collected within 14 days prior to and 28 days after the date of the initial positive blood donation.</td></tr> <tr> <td>Donors with a recent diagnosis of WNV infection.</td><td>Collected within 14 days prior to and 28 days after the onset of illness in the donor.</td></tr> </table>	If PDI is received about ...	Then promptly identify and locate all in-date products...	<ul style="list-style-type: none"> <li>• Donors with mild symptoms of upper respiratory infection unassociated with fever <b>OR</b></li> <li>• Donors with only mosquito bites</li> </ul>	NOT required or recommended.	Donors with an unexplained measured fever of >100.4 °F (>38°C) associated with headache or associated with other symptoms suggestive of WNV infection, occurring within 7 days prior to or 14 days after donation.	Collected within 14 days prior to and 28 days after the onset of symptoms in donor.	Donors testing confirmed positive for WNV NAT on a blood donation.	Collected within 14 days prior to and 28 days after the date of the initial positive blood donation.	Donors with a recent diagnosis of WNV infection.	Collected within 14 days prior to and 28 days after the onset of illness in the donor.
If PDI is received about ...	Then promptly identify and locate all in-date products...										
<ul style="list-style-type: none"> <li>• Donors with mild symptoms of upper respiratory infection unassociated with fever <b>OR</b></li> <li>• Donors with only mosquito bites</li> </ul>	NOT required or recommended.										
Donors with an unexplained measured fever of >100.4 °F (>38°C) associated with headache or associated with other symptoms suggestive of WNV infection, occurring within 7 days prior to or 14 days after donation.	Collected within 14 days prior to and 28 days after the onset of symptoms in donor.										
Donors testing confirmed positive for WNV NAT on a blood donation.	Collected within 14 days prior to and 28 days after the date of the initial positive blood donation.										
Donors with a recent diagnosis of WNV infection.	Collected within 14 days prior to and 28 days after the onset of illness in the donor.										

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# Policy on Blood Donor Screening, Deferral, and Lookback for West Nile Virus (WNV), Continued

## Lookback and Post Donation Information (continued)

Step	Action	
	<b>If PDI is received about ...</b>	<b>Then promptly identify and locate all in-date products...</b>
	Patients with recent diagnosis of WNV infection who received blood transfusions or organ donations within the 28 days preceding the onset of WNV symptoms.	Of all “suspect” donations that were transfused to the WNV patient <b>AND</b> all previous donations from the potentially associated donors that were collected within 28 days prior to and 28 days after the “suspect” donation(s).
	Donors suspected of being potentially associated with transfusion transmitted WNV infection in a recipient	Associated with “suspect” donation and all previous donations collected within 28 days prior to and 28 days after the “suspect” donation
2	Perform the following steps for product management, consignee notification, and recipient notification:	
	<b>If products are/were...</b>	<b>Then....</b>
	Available	Quarantine and destroy all blood products. Document disposition.
	Shipped	Notify consignee(s) to quarantine and destroy all products. Document notification.
	Destroyed	Document disposition.
	Transfused <b>AND</b> donor illness is a medical diagnosis of WNV	<u>Identify and Notify prior recipients</u> of the potential WNV transfusion risk. (Relevant units are those dating from 14 days prior through 28 days after the onset of illness of the donor).

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# Policy on Blood Donor Screening, Deferral, and Lookback for West Nile Virus (WNV), Continued

## Lookback and Post Donation Information (continued)

Step	Action	
	<b>If products are/were...</b>	<b>Then....</b>
	Transfused but donor illness is <b>NOT</b> medical diagnosis of WNV	<u>Do NOT</u> notify prior recipients of blood components collected from that donor.
	Transfused and potentially associated with transmission of WNV to a transfusion recipient, <b>but NOT confirmed</b> through epidemiological investigation	<u>Do NOT</u> notify prior recipients of blood components collected from that donor
	Transfused and the likely source of transmission of WNV to a transfusion recipient, <b>AND confirmed</b> through epidemiological investigation	<u>Identify and notify prior recipients</u> of blood components collected from that donor of the potential WNV transfusion risk. (Relevant units are those dating from 28 days prior to 28 days after the date of the donation that is implicated in transmission of WNV).
3	IAW Service procedures, notify local public health personnel and Service Blood Program Offices of donors diagnosed with or potentially infectious for WNV and of any transfusion recipients potentially at risk for WNV transfusion transmitted infection.	
4	Follow Service directed protocols for shipment of patient samples for further study. • Additional information on laboratory samples for CDC can be found at <a href="http://www.cdc.gov/ncidod/dvbid/westnile/clinical_guidance.htm">http://www.cdc.gov/ncidod/dvbid/westnile/clinical_guidance.htm</a>	
	<b>If samples are ...</b>	<b>Then ...</b>
	Needed for further testing	Ship IAW Service directions
	NOT needed	Discard IAW local policy

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# Policy on Blood Donor Screening, Deferral, and Lookback for West Nile Virus (WNV), Continued

## Lookback and Post Donation Information (continued)

Step	Action										
5	Document PDI and lookback IAW Service-specific SOPs.										
6	If donor is deferred, enter donor deferral in DBSS using temporary deferral code 906. (See Donor Screening and Deferral section of the document, for appropriate donor deferral criteria)										
7	Submit Biologic Product Deviation (BPD) reports, IAW Service SOPs, in instances of post-donation information related to WNV in cases where:										
	<table> <tr> <th>A suspect blood product ...</th><th>Then a BPD is ...</th></tr> <tr> <td>Was retrieved and quarantined as a result of a WNV PDI report</td><td>Required, contact Service Blood Program Office</td></tr> <tr> <td>Was transfused and resulted in notification of a transfusion recipient</td><td>Required, contact Service Blood Program Office</td></tr> <tr> <td>Was transfused and resulted in the fatality of a transfusion recipient</td><td>Required, contact Service Blood Program Office (SBPO)</td></tr> <tr> <td>NOT distributed</td><td>NOT required</td></tr> </table>	A suspect blood product ...	Then a BPD is ...	Was retrieved and quarantined as a result of a WNV PDI report	Required, contact Service Blood Program Office	Was transfused and resulted in notification of a transfusion recipient	Required, contact Service Blood Program Office	Was transfused and resulted in the fatality of a transfusion recipient	Required, contact Service Blood Program Office (SBPO)	NOT distributed	NOT required
A suspect blood product ...	Then a BPD is ...										
Was retrieved and quarantined as a result of a WNV PDI report	Required, contact Service Blood Program Office										
Was transfused and resulted in notification of a transfusion recipient	Required, contact Service Blood Program Office										
Was transfused and resulted in the fatality of a transfusion recipient	Required, contact Service Blood Program Office (SBPO)										
NOT distributed	NOT required										

## CDC Reporting Requirements

To assist in identification of other possible cases of WNV infection potentially associated with transfusion, the FDA also requires that:

If...	And...	Then...
Patient is diagnosed with WNV infection	Patient has received blood transfusion or organs within 28 days preceding onset of WNV symptoms	<ul style="list-style-type: none"> <li>Possible transfusion transmission of WNV should be reported to the CDC through local public health authorities. <b>AND</b></li> <li>Serum or tissue samples should be retained for later studies</li> </ul>

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## Policy on Blood Donor Screening, Deferral, and Lookback for West Nile Virus (WNV), Continued

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### CDC Reporting Requirements (continued)

If...	And...	Then...
Donor is diagnosed with WNV infection	Donor had onset of WNV symptoms within 14 days of blood or organ donation	<ul style="list-style-type: none"><li>• Possible transfusion transmission of WNV should be reported to the CDC through local public health authorities</li></ul>

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### Labeling of Products

Quarantined products that were distributed for research or intended for further manufacturing into Non-Injectable products, must be labeled consistent with recommended labeling described below as applicable:

- “Biohazard” **OR**
  - “Collected from a donor determined to be at risk for West Nile Virus” **OR**
  - “Collected from a donor positive for evidence of infection with West Nile Virus” **OR**
  - “For laboratory research use only” **OR**
  - “Intended only for further manufacturing into non-injectable products”
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## Donor Information About West Nile Virus (WNV)

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**What is WNV?** West Nile Virus infection has been associated with human encephalitis and meningitis. Throughout 2001 and 2002, WNV spread to about half of the US. In 2002, over 4000 cases of WNV illness and 277 deaths were reported. 99% of human cases in 2002 occurred between 2 July and 30 October.

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**How can I get WNV?** WNV is a mosquito borne virus that is primarily transmitted in birds through mosquito bites. WNV can also be transmitted from birds to humans through mosquito bites.

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**Can WNV be passed by blood transfusion?** Yes. The 2002 WNV epidemic involved the first documented cases of WNV transmission through blood transfusion, organ transplantation, from mothers to infants during pregnancy, and possibly during breastfeeding.

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**Can I donate blood today?** The Food and Drug Administration has recommended that donors who have a risk of being infected with WNV do not donate blood for a short interval.

You may NOT donate blood if you...	You must wait....
Had an unexplained measured fever of greater than 100.4 °F (38°C) associated with a headache within the last 7 days <b>OR</b>	At least 28 days from today's attempted donation date
Have been recently diagnosed with WNV infection <b>OR</b>	At least 28 days from the first day of WNV symptoms or until 14 days after the WNV illness is resolved
Have been notified that one of your blood donations tested positive for WNV	Until you are notified that you are eligible to donate again, but at least 28 days after the date of the confirmed positive donation.
Have been notified that one of your previous blood donations is the potential cause of WNV infection in a patient that has been transfused with your blood	At least 28 days after the date of that previous donation.

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**After you donate blood!** Thank for ensuring the safety of the blood supply! As long as you are well and remain well, you need not take any other measures. **However you should notify the blood donor center and see your doctor if:**

- In the 14 days after your donation, you become ill with a fever of 100.4 °F or higher **AND** have cold-flu symptoms **OR**
  - You later find out that you meet any of the other restrictions above.
-